Remarks/Arguments

Claims 1-20 stand rejected under 35 USC § 101, 35 USC § 112, 35 USC § 102 and 35 USC § 103. The claims have been amended to address the rejections under 35 USC § 112. Reconsideration and withdrawal of the other rejections is respectfully requested in view of the above amendments and for the reasons that follow.

Regarding 35 USC § 101, the Examiner holds that, based on Supreme Court precedent and recent Federal Circuit decisions, the claimed method is not (1) tied to another statutory class (such as a particular apparatus) or (2) does not transform underlying subject matter (such as an article or materials) to a different state or thing. The Examiner specifically notes that "The mere manipulation and production of non-functional descriptive material (i.e., "patient identifiers") is not a transformation because a patient identifier is not statutory subject matter."

While not specifically cited, the Examiner is apparently referring to the decision in *In re Bilski*, 545 F.3d 943, 88 U.S.P.Q.2d 1385 (Fed. Cir. 2008), which held that a process patent claim, in order to be patentable, must be "tied to a particular machine, or...transforms an article." In *Bilski*, the court specifically addresses what is meant by "transformation" of an "article" regarding data.

In its decision, the court stated that:

> "A claimed process is patent-eligible if it transforms an article into a different state or thing. This transformation must be central to the purpose of the claimed process. But the main aspect of the transformation test that requires clarification is what sorts of things constitute "articles" such that their transformation is sufficient to impart patent-eligibility under § 101."

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The court then went on to state that "The raw materials of many information-age processes, however, are electronic signals and electronically-manipulated data." The court then looked to earlier precedent for guidance in what was patent-eligible transformation of articles, noting that transformation of X-ray attenuation data into a particular visual depiction of a physical object on a display was sufficient for the claimed process to be patent-eligible.

In the rationale for its holding, the court noted that the claim was not required to involve any transformation of the underlying physical object that the data represented, noting that:

> "So long as the claimed process is limited to a practical application of a fundamental principle to transform specific data, and the claim is limited to a visual depiction that represents specific physical objects or substances, there is no danger that the scope of the claim would wholly pre-empt all uses of the principle."

Applicants' method is used to acquire information relating to potential clinical trial participants meeting predetermined criteria from a data source that includes the dictation records of at least one healthcare professional containing information relating to the medical conditions of a plurality of patients identified by non-personal identifiers. This information is then used by the healthcare professional initially contributing to the data source to contact prospective clinical trial participants, thereby preserving the patient's identity in compliance with HIPAA requirements.

The "article" transformed is a data source comprised of dictation records originated by one or more healthcare professionals. The "transformation", for which the dictation records were not originally intended, is the conversion of a segment of these dictation records into a list of potential clinical trial participants, which can later be used in recruiting of participants. The

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transformation is not, as the Examiner suggests, conversion into "patient identifiers". The patient identifiers, which are used by the healthcare professional to access the identified records, are added originally by the healthcare professional and are only used for the purpose of identifying the selected records in a manner meeting HIPAA requirements. Thus, data is being transformed into a selected list of records and there is "no danger that the scope of the claim would wholly pre-empt all uses of the principle."

With regard to the rejections under 35 USC § 102 and 35 USC § 103, Claims 1-9 and 11-15 stand rejected under 35 USC § 102 as being anticipated by Davies et al., while Claims 10 and 16-20 are rejected under 35 USC § 103(a) as unpatentable over Davies et al. in view of McAlindon et al. Reconsideration and withdrawal of the rejections is respectfully requested.

Some features of the Davies et al. reference are similar to features of the present invention. Davies et al. describe creation of a database of medical records that may include a physician's dictated notes. The database can be de-identified to remove personal information and to comply with HIPAA. The database can be used to identify subjects for a clinical trial.

However, as now clarified by the claims, at least two features of applicants' claimed invention are not taught or suggested by Davies et al. First, Davies et al. does not provide for any mechanism whereby patient information can be used by a research entity to develop prospects for clinical trials in which the research entity, defined in applicants' specification as clinical researchers and entities acting on behalf of clinical researchers, mines the data and then transmits non-patient identifiers for matching results to the healthcare professional originally entering the data for patient contact, with the names of favorably responding patients then being returned to the research entity.

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Second, as specifically defined in independent claims 1 and 16, and thereby the claims dependent thereon, the data source is specifically defined as "a data stream of individual patient records created during transcription of the dictation". As noted in applicants' specification as paragraph [0017], a unique aspect of the invention is to access a stream of data as it is generated by a channel vendor during transcription of healthcare provider dictation, thereby enabling review of a continuum of individual records as they are transcribed and shortly after they are dictated, as opposed to waiting until there is a database of multiple stored records. Contrary to the Examiner's assertions, Davies et al. does not teach accessing a data stream or any equivalent.

According to the Examiner, McAlindon teaches "receiving the names of patients who have consented to be interviewed regarding the clinical trial from said healthcare professional" and "contacting patients whose names are received from said healthcare professional". A careful reading of the McAlindon specification, and in particular column 4, lines 26-47 cited by the Examiner, show that this construction of the McAlindon teaching is not accurate.

In fact, McAlindon teaches a method to be used by clinical researchers in recruiting and qualifying participants via the Internet. In accordance with the McAlindon method, prospective participants are solicited through Internet advertising and then screened over the Internet with interactive questionnaires. Later, the prospect may be contacted by telephone by the researcher and assigned a unique username and password, which are provided by the researcher or picked by the prospect. No healthcare professional is actually involved and there is no exchange of information between the researcher and a healthcare professional.

McAlindon says nothing about accessing a data stream of individual patient records created during transcription of the dictation, and would have no need to access such a data stream

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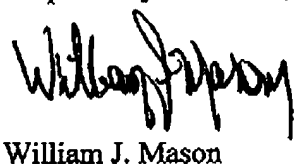
since the prospective participants are being identified in an entirely different manner.

Accordingly, in view of the amendments to the claims and for the foregoing reasons, it is believed that this application is now in condition for allowance. Issuance of a Notice of Allowance is respectfully requested.

Respectfully submitted,



William J. Mason
Registration No. 22,948

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